K080089

Section III - 510(k) Summary of Safety and Effectiveness

SEP - 4 2008

Submitter:

Sybron Dental Specialties, Inc.
1717 West Collins Drive
Orange, CA 92656
Colleen Boswell - Contact Person

Date Summary Prepared: January 2008

Device Name:

- Trade Name – ***SONICflex 2003 and SONICflex Lux 2003 L with Instrument Tips***
- Common Name – Ultrasonic Scaler
- Classification Name – Ultrasonic Scaler, per 21 CFR 872.4850

Devices for Which Substantial Equivalence is Claimed:

- Sirona Dental Systems GmbH, *SIROAIR L Air Scaler (K033812)*

Device Description:

The *SONICflex 2003 / SONICflex Lux 2003 L & Instrument Tips* consist of a handpiece, instrument tips, quick-action coupling and accessories for changing and cleaning the instrument tips. The handpieces are attached over a coupling and a hose to a dental operative unit. The power delivered to the handpiece is adjusted via a control ring located on the handpiece. The only difference between the *SONICflex 2003* and the *SONICflex Lux 2003 L* scaler is that the *SONICflex Lux 2003 L* has an integrated fiber optic. A variety of tips are available for specific dental applications and for reaching different areas of the mouth. The devices can be sterilized by the steam autoclave method.

Intended Use of the Device:

The *SONICflex 2003 and SONICflex Lux 2003 L with Instrument Tips* are air-powered scalers intended for use in following areas:

• Scaling:	• Tooth scaling and cleaning • Tooth neck and subgingival treatment
• Periodontics:	• Root planning • Initial therapy • Implant maintenance
• Endodontics:	• Canal preparation and cleaning • Micro retro surgery
• Prosthesis:	• Inlay / onlay condensation • Fissure cleaning • Minimal invasive cavity cleaning

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Substantial Equivalence:

The *SONICflex 2003 and SONICflex Lux 2003 L* air-scalers are substantially equivalent to other legally marketed devices in the United States. The intended use of the devices is similar to that of the predicate. The *SONICflex 2003 and SONICflex Lux 2003 L* air-scalers are substantially equivalent in design, application and function to the SIROAIR L Air Scaler marketed by Sirona Dental Systems GmbH.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 4 2008

Ms. Colleen Boswell
Vice President, Regulatory Affairs
Sybron Dental Specialties, Incorporated
1717 West Collins Avenue
Orange, California 92867

Re: K080089
Trade/Device Name: SONICflex 2003 and SONICflex Lux 2003 L with Instrument Tips
Regulation Number: 21 CFR 872.4850
Regulation Name: Ultrasonic Scaler
Regulatory Class: II
Product Code: ELC
Dated: August 29, 2008
Received: September 2, 2008

Dear Ms. Boswell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address. http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Samuel Lin, for

Chiu S. Lin, Ph. D
Division Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K080089

Indications for Use

510(k) Number (if known):

Device Name: *SONICflex 2003 and SONICflex Lux 2003 L with Instrument Tips*

Indications for Use:

The *SONICflex 2003 and SONICflex Lux 2003 L with Instrument Tips* are air-powered scalers for use by qualified dental practitioners in the four conventional dental applications of scaling, periodontics, endodontics and prosthesis.

Prescription Use X AND/OR Over-The-Counter Use

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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